

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 33rd meeting held on 25.05.2017 at CDSCO HQ New Delhi:

Agenda no.	File no./Drug Name	Name of firm/Institute	Recommendations
Fixed Dose Combination Division			
1	4-87/2000-DC (Pt-Cipla) Lopinavir 40mg/Ritonavir 10mg Pellets (Capsules)	M/s. Cipla	Due to extreme difficulties like finding the patients, suitable institutions and ethical issues to conduct feasibility studies in pediatric population in India in private settings, prior to the approval of the product, committee recommended approval of the product {Lopinavir 40mg/Ritonavir 10mg Pellets (Capsules)} with the condition that NACO will conduct Post Marketing Surveillance in first 100 patients and submit the data. The questionnaire and protocol developed for this surveillance will be submitted to CDSCO by the firm.
2	04-20/2016-DC (Pt.Mylan) Tenofovir Disoproxil Fumarate IP+Lamivudine IP+Efavirenz IP (300 mg+300mg+400mg)	M/s. Mylan Laboratories	The firm presented the protocol of the phase IV clinical trial. The committee after detailed deliberation recommended for grant of permission to manufacture Tenofovir Disoproxil Fumarate IP+Lamivudine IP+Efavirenz IP (300 mg+300mg+400mg) tablet subject to the condition that the firm shall conduct the phase IV clinical trial as per protocol submitted with following recommendations: 1. The efficacy should be assessed at 24 weeks only. 2. CYP2B6 polymorphism and levels of Efavirenz should be assessed in atleast 10% of geographically representative samples of the participants. 3. Proper monitoring should be ensured for strict adherence of the participants with the treatment schedule. 4. The firm shall ensure accessibility of the product for all the participants for atleast 6 months after completion of the study.
3	04-20/2017-DC (Pt. Mylan) Abacavir Sulphate USP eq. to Abacavir + Lamivudine USP (60mg+30mg)	M/s. Mylan Laboratories	The FDC of Abacavir Sulphate USP eq. to Abacavir + Lamivudine USP (600mg+300mg) is already approved and the firm conducted BE study with this product. Active ingredients and the excipients in the proposed product {film coated tablet of

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			Abacavir Sulphate USP eq. to Abacavir + Lamivudine USP (60mg+30mg) }and the approved product are in same proportion. After detailed deliberation committee recommended for grant of permission to manufacture Abacavir Sulphate USP eq. to Abacavir + Lamivudine USP (60mg+30mg) tablet.
4	04-32/2017-DC Part A: One film coated tablet of Dolutegravir tablet & Part B: One film coated tablet of Abacavir Sulhate IP eq. to Abacavir + Lamivudine Tablet IP (50mg & 600mg+300mg)	M/s. Emcure Pharmaceuticals	The firm presented various guidelines recommending concomitant use of Dolutegravir, Lamivudine and Abacavir in patients with HIV infection. The drugs are also approved individually in the country. After detailed deliberation the committee recommended for the grant of permission to manufacture the proposed combikit for the treatment of HIV infection in adults weighing more than 40kg.
5	04-40/2017-DC Part A: One film coated tablet of Dolutegravir tablet & Part B: Bilayered film coated tablet of Lamivudine Tablet IP + Tenofovir Disoproxil Fumarate IP (50mg & 300mg+300mg)	M/s. Emcure Pharmaceuticals	The firm presented various guidelines recommending concomitant use of Dolutegravir, Lamivudine and Tenofovir in patients with HIV infection. The drugs are also approved individually in the country. After detailed deliberation the committee recommended for the grant of permission to manufacture the proposed combikit for the treatment of HIV infection in adults weighing more than 40kg.
New Drugs Division			
6	12-34/12-DC Arbekacin Sulphate Injection 200mg/4ml	M/s. Alkem	The firm presented the Phase III Clinical Study report of Arbekacin sulphate injection 200mg/4ml along with other information on the proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product subject to condition that the firm should strictly monitor the safety of the drug through post marketing surveillance.
Subsequent New Drugs Division			
7	12-18/2017-DC (Pt- Themis-SND) Artesunate for injection with DEGEE buffer 60 mg (IV/IM)	M/s. Themis Medicare Limited	This subject product contains the DEGEE as a solubilising agent. The committee noted that the safety issue of DEGEE is under examination by a committee constituted by Ministry of Health and Family Welfare and the matter is also in Delhi high court.

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			Therefore the committee opined that at this point of time it is not proper to consider the proposal.
8	12-38/2014-DC (Pt-Themis-SND) Alpha-beta Arteether IV injection 75 mg/ml for injection (IV/IM)	M/s. Themis Medicare Limited	This subject product contains the DEGEE as a solubilising agent. The committee noted that the safety issue of DEGEE is under examination by a committee constituted by Ministry of Health and Family Welfare and the matter is also in Delhi high court. Therefore the committee opined that at this point of time it is not proper to consider the proposal.